

## **REMARKS**

### **The Amendments**

The claims are replaced with new claims to better conform them to U.S. practice including addressing objections made in the Office Action.

The amendments do not narrow the scope of the claims and/or were not made for reasons related to patentability. The amendments should not be interpreted as an acquiescence to any objection or rejection made in this application. To the extent that the amendments avoid the prior art, competitors are warned that the amendments are not intended to and do not limit the scope of equivalents which may be asserted on subject matter outside the literal scope of any patented claims but not anticipated or rendered obvious by the prior art. Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

### **The Objection to the Oath/Declaration**

The Declaration is not defective. The sixth-named inventor, Ms. Habenicht, merely signed in the incorrect box (i.e., the one for a 12<sup>th</sup> inventor rather than the 6<sup>th</sup>). There are only six named inventors which is evident from the declaration and application papers. Thus, there is no missing information for a 12<sup>th</sup> inventor, since there is no 12<sup>th</sup> inventor, and the signature of the 6<sup>th</sup> inventor is not missing, since it is merely in the wrong adjoining box. That it is the correct signature of the 6<sup>th</sup> inventor is believed to be evident from the document as a whole and such minor placement error should not make the document defective. All the information and signatures are present and the correction of the obvious error is clear. It is

noted that no statute or rule requires that the inventors' signatures be in a particular box. It is sufficient that the required information can be matched to each inventor and that the signature of each is provided. The submitted Declaration meets the requirements and should be accepted.

### **The Objection to the Specification**

Applicants are preparing a more legible copy of page 20, Table 1, and will submit it by Supplemental Amendment shortly.

### **The Rejections under 35 U.S.C. §112, second paragraph, and 35 U.S.C. §101**

The rejections under 35 U.S.C. §112, second paragraph, and 35 U.S.C. §101 are believed to be rendered moot by the replacement of the claims with new claims not containing the objected to language.

### **The Rejections under 35 U.S.C. §102 and 35 U.S.C. §103 over Guerin**

The rejection of claims 1-56 either under 35 U.S.C. §102, as being anticipated, or under 35 U.S.C. §103, as being obvious, over Guerin (Intnl. J. Andrology) are respectfully traversed.

Guerin relates to compositions and methods for male contraception utilizing hormones which are administered daily. Guerin teaches only the following three hormone combinations and routes for administration (see the Summary, p. 187):

- a) daily MPA progestin orally combined with daily testosterone or 5 $\alpha$ -dihydrotestosterone percutaneously;

- b) daily norethisterone acetate (5 mg twice daily or 10 mg once daily) orally combined with daily testosterone percutaneously; and
- c) daily norethisterone acetate combined with testosterone undecanoate, both administered orally.

The Guerin methods thus relate only to three specific manners of oral administration of a progestogen in combination with oral or percutaneous administration of an androgen.

The current independent claims 57, 76, 91, 105 and 120 are not anticipated by this disclosure of Guerin.

Guerin fails to teach a composition, or process using it, with testosterone undecanoate formulated for non-oral administration. Compare, e.g., claims 57 and 105.

Guerin fails to teach a composition comprising a norethisterone derivative (NET derivative) possessing both androgenic and estrogenic properties wherein the effective amount of said NET derivative is such that the effective levels in blood are sustained for not less than 1 week. Guerin relates only to daily administered hormones, thus, the hormones would not be provided in an amount such that upon administration effective levels in the blood that are sustained for not less than 1 week. One of ordinary skill in the art would consider that Guerin teaches using its hormones in amounts providing only effective levels in the blood sustained for about 1 day. Compare, e.g., instant claims 76, 91 and 120.

Similarly, Guerin fails to teach a composition or process using it wherein an androgen is provided in an effective amount such that the effective levels in blood are sustained for not less than 1 week. Compare, e.g., instant claims 76 and 120.

For these reasons, at least, Guerin cannot anticipate any of the instant independent claims 57, 76, 91, 105 or 120 and therefore cannot anticipate any of the instant claims.

The claims compositions and methods are also not obvious in from the teachings of Guerin.

The objective of Guerin was to provide a male contraception regimen for ease of administration; see top of page 188. For the embodiment of Guerin using testosterone undecanoate, the reference teaches only oral administration (see, e.g., page 188, lines 20 to 22), which would be the preferred administration route of greatest ease. Guerin would, thus, provide no motivation to one of ordinary skill in the art to compositions and methods for non-oral administration of testosterone undecanoate, i.e., one of ordinary skill in the art would not be motivated to go away from oral administration in view of Guerin's objective of ease of administration. For this reason, at least, claims 57 and 105 (and claims dependent thereon) are not obvious over Guerin.

Further, Guerin does not suggest a male contraceptive formulation, composition or method for other than daily administration. The only teachings in the reference relate to daily administration and there is no suggestion in the reference for other than daily administration or any teaching as to how to effectively achieve other than daily administration methods. Thus, Guerin cannot suggest a formulation/composition capable of exerting male contraception activity for not less than 1 week or a method wherein the hormones are administered at intervals of not less than 1 week, let alone at a 4 or 5 week interval. Accordingly, Guerin cannot suggest the compositions or methods of instant independent claims 76, 91 and 120 (or claims dependent thereon). Advantageously over the prior art compositions and methods which require daily administration, the invention of these claims requires the patient only to take the hormones once weekly or less. Thus, a significant advance in the art is provided.

For all of the above reasons, it is submitted that Guerin fails to render any of the instant claims obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. §103, as well as §102, should be withdrawn.

**The Rejections under 35 U.S.C. §102 and 35 U.S.C. §103 over Spona**

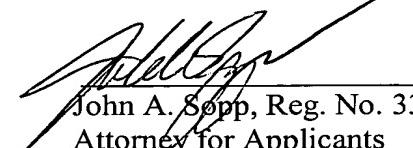
The rejection of claims 1-10, 11 and 12 under 35 U.S.C. §102, as being anticipated, or under 35 U.S.C. §103, as being obvious, over Spona (U.S. Patent No. 5,583,129) are respectfully traversed.

Spona et al relates to female contraception by administering a progestogen, for example norethisterone. Spona et al does not teach or suggest methods for male contraception, administration of a combination of a progestogen and an androgen, compositions comprising a combination of a progestogen and an androgen, or formulations comprising a NET derivative. There would be no motivation to one of ordinary skill in the art to modify Spona to include an androgen in its compositions since Spona is directed to female contraception. It is noted that the current claims are directed to subject matter which was not rejected over Spona in the Office Action. Thus, it is believed to be clear that Spona is not longer applicable against the instant claims and the rejections based on Spona should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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